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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Matthew P. Carter

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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05/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,589

Applicant(s)

CARTER ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendments received on 06 March 2007.

Corrections made to the claims are accepted.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 30 recites the limitation "providing a first stent and a second stent in an adjacent configuration ...the adjacent configuration having an overall diameter that is less than the sum of a first stent portion diameter and a second stent portion diameter." It is unclear as to how an overall diameter of *adjacent* stents can be less than the sum of their diameters. Since claims 31 and 32 depend from claim 30, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Eidenschink (Publication No. 2005/01922656 A1). Eidenschink discloses a method of placing first and second stents into a bifurcation using a stent delivery device (see entire document) comprising the steps of providing a first introducer (for example, see Figures 6A and 6B; 38) having a first distal outer diameter and a second introducer (36) having a second distal outer diameter, and placing the first introducer (38) and second introducer (36) in an adjacent configuration. Since the first (38) and second (36) introducers have a constant diameter from the proximal through the distal portions, the overall diameter of the first (38) and second (36) introducers is inherently less than the sum of their distal ends.

Eidenschink further discloses the steps of placing a first (26) and second (28) wire guide in an adjacent configuration, placing a first wire guide (26) into a main lumen (12) and a first branch lumen (14), placing a second wire guide (28) into a main lumen and a second branch lumen (16), and advancing first (38) and second (36) introducers over the first (26) and second (28) wire guides such that the first (38) and second (36) introducers are simultaneously positioned within the main lumen (12) and the first (14) and second (16) branch lumens, and such that the first distal portion is distal to the second distal portion (since they are situated away from each other; paragraph 41).

5. Claims 26, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorros (Patent No. 5,720,735). Dorros discloses a method of placing stents within branch lumens and a main lumen (see entire document) comprising the steps of providing a first introducer (for example, see Figure 5; 18) having a first stent (64), providing a second introducer (20) adjacent to the first introducer having a second stent (66), placing a first (28) and second (30) wire guide into the main lumen (not labeled; ends at the apex of the "V" portion) and the first (40) and second (42) branch lumens, advancing the first and second introducers over the first (28) and second (30) wire guides such that the first and second introducers are simultaneously positioned within the main lumen and the first (40) and second (42) branch lumens, and deploying the first stent (64, Figure 9; column 6, lines 26-30 and 42-46).

Referring to Figure 5, the distal portions of the first (18) and second (20) introducers have a constant diameter from the proximal portions to the distal portions. The distal portions comprise tapered distal tips, wherein the tapered distal portions have a larger diameter than the diameter of the proximal portions of the introducers. Therefore, when the first (18) and second (20) introducers are disposed in adjacent configuration (for example, at a point within the main lumen before advancing into the bifurcation), the adjacent configuration has an overall diameter inherently less than the sum of the first and second distal diameters. Figure 5 further shows the first proximal outer portion is disposed *adjacent to* the second distal portion.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros in view of Carleton (Patent No. 6,142,973). Dorros discloses a method as described above, however fails to disclose simultaneously deploying the stents. Carleton discloses a method of deploying stents (see entire document). Carleton teaches the step of simultaneously deploying a first (128) and second (130) stent (for example, see Figure 5 and column 6, lines 38-43). Furthermore, Dorros discloses an introducer assembly comprising an alternate embodiment comprising a single lumen capable of deploying a first and second stent simultaneously (for example, see Figure 4 and column 5, lines 57-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simultaneously deploy the stents of Dorros as taught by Carleton

in order to facilitate the treatment of lesions in branched or bifurcated arteries (column 1, lines 40-67).

9. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman (Publication No. 2006/0100694 A1) in view of Killion et al. (Patent No. 6,159,238). Globerman discloses a method of placing stents within branch lumens and a main lumen (see entire document) comprising the steps of positioning the first (for example, see Figures 2A-2F; 210) and second (220) stents within the first (103) and second (104) branches such that the distal portions extend at least partially within the first (103) and second (104) branch and the proximal portion extends at least partially within the main lumen (118), providing an open access to the second branch (104) as the first stent (210) is positioned, deploying the first (130) and second (128) stents (see Figures 2A-F and paragraphs 111-122), and providing a first (210) and second (220) stent in an adjacent configuration, wherein the first stent (210) is distal to the second stent (220). However, Globerman fails to disclose that the adjacent configuration has an overall diameter that is less than the sum of the first and second stent portions.

Stents of having variable diameters are well known in the art. Killion discloses a method of deploying stents (see entire document). Killion teaches utilizing stents having variable diameters in bifurcated vessels (for example, see column 1, lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize stents having a variable diameter in the method of Globerman in order to provide outward radial forces that match the local force requirements, thus reducing the risk of damaging healthy tissue (for example, see column 3, lines 48-59). Furthermore,

placing stents having variable diameters in an adjacent configuration would provide an overall diameter at a point having the smallest diameter that is less than the sum of a first stent portion at a point having the largest diameter and a second stent portion at a point having the largest diameter.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman in view of Killion as applied to the claims above, and further in view of Carleton. Globerman in view of Killion discloses a method as described above, however, fails to disclose simultaneously deploying the first and second stents. Carleton discloses a method of deploying stents (see entire document). Carleton teaches the step of simultaneously deploying a first (128) and second (130) stent (for example, see Figure 5 and column 6, lines 38-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simultaneously deploy the stents of Globerman in view of Killion as taught by Carleton in order to facilitate the treatment of lesions in branched or bifurcated arteries (column 1, lines 40-67).

11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eidenschink in view of Mikus et al. (Publication No. 2002/0035391 A1). Eidenschink discloses a method as described above, however, does not disclose the step of providing an endoscope having a working channel. Mikus et al. disclose a stent delivery system (Figure 2), wherein an endoscope (19) with a working channel (28) is provided. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an endoscope with a working channel in the method of

Eidenschink as taught by Mikus et al. in order to be able to locate the stent placement through direct vision (paragraph 6).

Response to Arguments

12. Applicant's arguments filed 06 March 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art references utilized do not teach the limitations that have been added to the amended claims. Examiner respectfully disagrees. It is noted, however, that the arguments regarding amended claim 30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues specifically that Eidenschink does not teach or suggest a reduced diameter required by claim 24 and that Dorros does not teach or suggest a reduced overall diameter required by claim 26. Regarding amended claim 24, the adjacent configuration does not require *a reduced diameter*, but rather requires that the *overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter*, which Eidenschink discloses (see rejection above). Regarding amended claim 26, the adjacent configuration does not require *an overall reduced diameter*, but rather requires an *adjacent configuration having an overall diameter that is less than the sum of a first distal outer diameter and a second distal outer diameter*, which Dorros discloses (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
May 14, 2007

MT

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(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

5/24/07